UNITED STATES PATENT AND TRADEMARK OFFICE

4/C

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,960	11/17/2000	Weihong Xiong	T8345.NP	4286

20551 7590 09/21/2004

THORPE NORTH & WESTERN, LLP.
8180 SOUTH 700 EAST, SUITE 200
P.O. BOX 1219
SANDY, UT 84070

EXAMINER	
WINSTON, RANDALL O	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/944,960	XIONG ET AL.	
	Examiner	Art Unit	
	Randall Winston	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/17/2000*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *1-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0901 and 0501*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, claims 50-54 in the reply filed on 07/19/2004 is acknowledged.

Examiner acknowledges that claims 1-49 are withdrawn. Claims 50-54 will be examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 50-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant" must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is "*whatever is now claimed*" (see

page 1117).

A review of the language of the claims indicates that claims 50-54 are drawn to a genus of an "aconitine alkaloid".

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention".

There is a single species of the claims 50-54 genus disclosed within the specification that is within the scope of the claimed genus of an "aconitine alkaloid". The specification on page 24 lines 25-26 and page 25 lines 1-3 discloses the single species such as "lappaconitine" "3-acetylaconitine" "bulleyaconitine" that is within the claimed genus of an "aconitine alkaloid".

The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claims 50-54 encompass numerous species that are not further described. There is substantial variability among the species.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of which comprises of an "aconitine alkaloid".

The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 50-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for a method of ameliorating pain and inflammation in a subject comprising transdermally administering to said subject an effective amount of lappaconitine (i.e. claimed amount of 4-10mg) and/or 3-acetylaconitine (i.e. claimed amount of .2-1 mg) and/or bulleyaconitine (i.e. claimed amount of .2-2), the specification does not enable any person in the art

for preparing a method of ameliorating pain and inflammation in a subject comprising transdermally administering to said subject any/or every amount of any/or all aconitine alkaloid to achieve the claimed blood plasma level.

The factors to be considered in determining whether undue experimentation is required are summarized in In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; © the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicant claims a method of ameliorating pain and inflammation in a subject comprising transdermally administering to said subject any/or every amount of any/or all aconitine alkaloid to achieve the claimed blood plasma level of a particular range. Applicant has reasonably demonstrated on page 24 lines 25-26 and page 25 lines 1-3 of the specification a method of ameliorating pain and inflammation in a subject comprising transdermally administering to said subject an effective amount of lappaconitine (i.e. claimed amounts of 4-10mg) and/or 3-acetylaconitine (i.e. claimed amounts of .2-1 mg) and/or bulleyaconitine (i.e. claimed amounts of .2-2 mg). Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a method of ameliorating pain and inflammation in a subject comprising transdermally

administering to said subject any/or every amount of any/or all aconitine alkaloid to achieve the claimed blood plasma level of a particular range.

Moreover, it should be noted that the state of the prior art at the time the invention was filed did not recognize a method of ameliorating pain and inflammation in a subject comprising transdermally administering to said subject any/or every amount of any/or all aconitine alkaloid to achieve the claimed blood plasma level of a particular range. For example, Murayama teaches (US 5,7705604, see, e.g. abstract, column 1 lines 63-67, column 3 lines 4-18 and example 4) a method of ameliorating pain and inflammation in a subject comprising transdermally administering to said subject an effective amount of (i.e. 30mg/10ml) of an aconitine alkaloid (i.e the aconitine alkaloids of Table 1). Thus, the art is silent regarding the efficacy of applicant's method of ameliorating pain and inflammation in a subject comprising transdermally administering to said subject any/or every amount of any/or all aconitine alkaloid to achieve the claimed blood plasma level of a particular range. Therefore, applicant's claimed method is unpredictable in the art.

Furthermore, applicant's specification has reasonably demonstrated on page 24 lines 25-26 and page 25 lines 1-3 of the specification a method of ameliorating pain and inflammation in a subject comprising transdermally administering to said subject an effective amount of lappaconitine (i.e. claimed amounts of 4-10mg) and/or 3-acetylaconitine (i.e. claimed amounts of .2-1 mg) and/or bulleyaconitine (i.e. claimed amounts of .2-2 mg). Applicant's specification, however, has failed to provide guidance or working examples

whereby applicant prepares a method of ameliorating pain and inflammation in a subject comprising transdermally administering to said subject any/or every amount of any/or all aconitine alkaloid to achieve the claimed blood plasma level of a particular range.

Therefore, it would require undue experimentation by one of skill in the art to practice the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 50-54 are rejected under 35 U.S. C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 50 is rendered vague and indefinite by the phrase "a method of ameliorating pain and inflammation comprising transdermally administering." It is unclear to examiner to who the claimed compound is being administered to. For example, is the claimed compound being administered to said human and/or to said subject and/or to said patient in need thereof.

Claim 50 is rendered vague and indefinite by the term "an amount." It is unclear to examiner of what effective amounts are being administered to a subject to ameliorate pain and inflammation in said subject except for the three enabled compositions of "lappaconitine", "3-acetylaconitine" and "bulleyaconitine" because one of ordinary skill in the art would know that any/or every amount of the claimed compound would not be sufficient to achieve the claimed results.

(Please note: Applicant is claiming possession of any/or every amount of the claimed compound to be sufficient to achieve the claimed results which is not possible especially in the absence of evidence to the contrary.)

One of ordinary skill in the art would not know if they were in possession of the claimed amounts since there is a lack of guidance in the specification as well as the prior art as to what amounts will achieve the claimed results.

All other claims depend directly or indirectly from the rejected claims and are, therefore, also rejected under 356 U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 50-54 are rejected under 35 U.S.C. 102(b) as being unpatentable anticipated by Liu J-H et al. (*Anti-Inflammatory and Analgesic Activities of N-Deacetyllappaconitine and Lappaconitine*, Acta Pharmacologica Sinica, (1987), Vol. 8, No. 4, pp. 301-305.)

Applicant claims a method of ameliorating pain and inflammation in a subject comprising transdermally administering to said subject an effective amount of lappaconitine (i.e. claimed amounts of 4-10 mg).

Liu J-H et al. anticipate (see, e.g., abstract) the claimed invention because Liu J-H et al. teach a method of ameliorating pain and inflammation in a subject comprising transdermally administering to said subject an effective amount of 1-6 mg of lappaconitine to said subject.

{Please note that transdermally is the same as injecting wherein the reference is injecting the subject with the claimed compound}

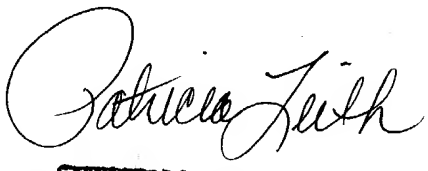
Moreover, although the Liu J-H et al. reference is silent in regards to "transdermally administering an amount of lappaconitine sufficient to achieve the claimed invention's lappaconitine blood plasma level ranges, the Liu J-H et al.'s administered lappactonitine must achieved the claimed invention's lappaconitine blood plasma level ranges because the Liu J-H's administered amount is the same as the claimed invention's administered amount whereas the same administered amount would inherently achieve the same results.

Therefore, the reference anticipates the instant claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



PATRICIA LEITH
PRIMARY EXAMINER